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WSJ: Critical HIV Prevention Study Halted

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A highly-anticipated trial to determine whether existing AIDS drugs can ward off HIV infection in women has been stopped early, in a setback in the search for ways to prevent the disease.

Researchers said Monday they had called off the trial among high-risk women in Africa because they weren't able to determine whether use of antiretroviral medication produced any benefit. The study tested whether taking the medication once a day could prevent uninfected women from contracting the HIV the virus, estimated to infect more than 2.5 million people each year.

Several researchers lamented the result as "disappointing" -- and surprising, because virtually the same prevention method was proven successful just last year in a large, multicountry trial among gay men. Researchers speculated that physiological differences between men and women might be at play, or that participants in the women's trial might not have adhered to the regimen as closely as the gay men did.

The early halt to the trial is particularly frustrating, because it leaves unanswered the fundamental question of whether the intervention works in women, researchers said. But at least two other studies in Africa are ongoing which could answer the question of whether AIDS drugs taken orally can prevent HIV infection in women.

(This story and related background material will be available on The Wall Street Journal website, WSJ.com.)

In another surprise finding, women in the study taking the antiretroviral medication were more likely to get pregnant than women taking a placebo. This was true despite the fact that 96% of women in the study were on oral or injectable contraceptives when the study began.

There is no known interaction between the antiretroviral drugs and hormone contraceptives, researchers in the study said. They said they will analyze their data to try to tease out if there is might be such an interaction.

Pregnancies were highest among women taking oral contraceptives, as opposed to longer-lasting injectables, raising the possibility they conceived because they had lapsed in taking their contraceptive pills.

Because the study was stopped early, researchers are finishing collecting the data. They will then analyze it to try to answer the lingering questions.

The randomized, placebo-controlled trial, called FEM-PrEP, was carried out among 1,951 women in South Africa, Kenya, and Tanzania by FHI, a non-profit global health and development organization, with major funding from the U.S. Agency for International

Development, or USAID, and additional funding from the Bill and Melinda Gates Foundation. Approximately half the women were given Truvada, a pill that combines two antiretroviral medications, tenofovir and emtricitabine; the other half were given a placebo. Fifty-six infections occurred overall, with exactly half among women taking placebo and half among women taking the active drug.

Truvada is marketed worldwide by Gilead Sciences Inc., headquartered in Foster City, Calif. In a written statement Monday, the company said, "While this development is a disappointing one, Gilead believes that antiretroviral therapies remain a promising potential HIV prevention strategy ... We continue to support ongoing studies evaluating the company's antiretroviral therapies as potential preventatives."

Clinical trials are typically reviewed at regularly scheduled intervals by an independent committee that evaluates safety and determines if, given the data at that point, the trial can answer the questions it set out to answer. Such a committee reviewed the FEM-PrEP data and decided that, statistically, the trial could not determine if Truvada reduces the risk of HIV infection. So the committee recommended closing the trial.

The committee's report isn't public, according to Timothy Mastro, a FHI vice president who spoke on behalf of the study. But he said the committee commended the researchers for running the trial well and ethically.

Last year, a study of once-daily Truvada among gay and bisexual men showed that it reduced the chance of infection by about 44%. Normally, the rectum is more susceptible to HIV than the vagina. However, it is possible that the women in this study may have had concurrent sexually-transmitted infections or irritation in the vaginal lining, increasing their vulnerability to infection, said Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases. Dr. Fauci wasn't involved in this study but has followed it closely.

Dr. Mastro said there is also research, as yet unpublished, showing that the concentration of tenofovir, when taken orally, is higher in rectal tissue than in vaginal tissue, meaning that the men might have had more of the drug at the site where they were exposed to the virus than the women.

Dr. Fauci said that adherence would have to be examined very carefully through such measures as testing stored blood samples to see if drug was in their bodies. Researchers said they planned such analyses.

The U.S. Centers for Disease Control and Prevention issued a statement Monday reaffirming that Truvada should be considered for use only among gay and bisexual men who are at high risk of contracting HIV, and delivered together with other prevention services.

Last year, another highly-celebrated trial in South Africa showed that women could be protected against HIV by applying to their vaginas before and after sex a gel containing tenofovir, one of the two medications in the pill taken by the women in the latest study.

However, there could be a big difference between taking that medication orally and applying as a gel directly. Research presented earlier this year at the Conference on Retroviruses and Opportunistic Infections showed that tenofovir concentrations in vaginal tissue were about 100 times higher when the drug was applied in the gel form compared to when it was taken orally. That study, the researchers concluded, raises "concern about the relative efficacy of oral dosing to prevent vaginal transmission." [04-18-11 1428ET]

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